UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALAN MAUSKOPF, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. MESOBLAST LIMITED, SILVIU ITESCU, and JOSH MUNTNER, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Alan Mauskopf ("Plaintiff"), individually and on behalf of all others similarly situated, by and through Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, the investigation conducted by Plaintiff's counsel, which includes without limitation: (a) review and analysis of regulatory filings made by Mesoblast Limited ("Mesoblast" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Mesoblast; and (c) review of other publicly available information concerning Mesoblast.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Mesoblast securities between April 16, 2019 and October 1, 2020, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Mesoblast develops allogeneic cellular medicines using its proprietary mesenchymal lineage cell therapy platform. Its lead product candidate, RYONCIL (remestemcel-L), is an investigational therapy comprising mesenchymal stem cells derived from bone marrow. In February 2018, the Company announced that remestemcel-L met its primary endpoint in a Phase 3 trial to treat children with steroid refractory ("SR") acute graft versus host disease ("aGVHD").

3. In early 2020, Mesoblast completed its rolling submission of its Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") to secure marketing authorization to commercialize remestemcel-L for children with steroid refractory aGVHD.

4. On August 11, 2020, the FDA released briefing materials for its Oncologic Drugs Advisory Committee ("ODAC") meeting to be held on August 13, 2020. Therein, the FDA stated that Mesoblast provided post hoc analyses of other studies "to further establish the appropriateness of 45% as the null Day-28 ORR" for its primary endpoint. The briefing materials stated that, because of design differences between these historical studies and Mesoblast's submitted study, "it is unclear that these study results are relevant to the proposed indication."

5. On this news, the Company's American Depositary Share ("ADS") price fell $6.09 per share, or approximately 35%, to close at $11.33 per share on August 11, 2020, on unusually heavy trading volume.

6. On October 1, 2020, Mesoblast disclosed that it had received a Complete Response Letter ("CRL") from the FDA regarding its marketing application for remestemcel-L for treatment of SR-aGVHD in pediatric patients. According to the CRL, the FDA recommended that the Company "conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD." The CRL also "identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity."

7. On this news, the Company's ADS price fell $6.56 per share, or over 35%, to close at $12.03 per share on October 2, 2020, on unusually heavy trading volume.

8. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) comparative analyses between Mesoblast's Phase 3 trial and three historical studies did not support the effectiveness of remestemcel-L for steroid refractory aGVHD because of design differences

between the four studies; (ii) as a result, the FDA was reasonably likely to require further clinical studies; (iii) as a result, the commercialization of remestemcel-L in the U.S. was likely to be delayed; and (iv) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff , as set forth in the accompanying Certification, incorporated by reference herein, purchased Mesoblast securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Mesoblast is incorporated under the laws of Australia with its principal executive offices located in Melbourne, Australia. Mesoblast's ADSs trade in an efficient market on the NASDAQ exchange ("NASDAQ") under the symbol "MESO."

16. Defendant Silviu Itescu ("Itescu") was the Company's Chief Executive Officer at all relevant times.

17. Defendant Josh Muntner ("Muntner") was the Company's Chief Financial Officer at all relevant times.

18. Defendants Itescu and Muntner (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

19. Mesoblast develops allogeneic cellular medicines using its proprietary mesenchymal lineage cell therapy platform. Its lead product candidate, RYONCIL (remestemcel-L), is an investigational therapy comprising mesenchymal stem cells derived from bone marrow.

20. On February 21, 2018, Mesoblast announced that the Phase 3 trial for remestemcel-L in children with steroid refractory aGVHD had met its primary endpoint. Specifically, the Company issued a press release entitled "Primary Endpoint Successfully Achieved in Mesoblast's Phase 3 Cell Therapy Trial for Acute Graft Versus Host Disease," in which it stated[1]:

> Mesoblast . . . today announced that the Phase 3 trial of its allogeneic mesenchymal stem cell product candidate ***MSC-100-IV (remestemcel-L) in children with steroid refractory acute Graft versus Host Disease (aGVHD) has successfully met the primary endpoint of Day 28 overall response (OR, complete + partial response) rate***.
>
> In the 55 children enrolled in Mesoblast's open-label Phase 3 trial conducted across 32 sites in the United States, the Day 28 OR rate was 69%, a statistically significant increase ***compared to the protocol-defined historical control rate of 45% (p=0.0003).***
>
> Among patients who received at least one treatment infusion and were followed up for 100 days (n=50), the mortality rate was 22%. This is in contrast to Day 100 mortality rates as high as 70% in patients who fail to respond to initial steroid therapy.
>
> The treatment regimen of remestemcel-L was well tolerated and the incidence of adverse events was consistent with that expected from the underlying disease state and in line with previous remestemcel-L use.
>
> These safety and efficacy results are consistent with Mesoblast's prior experience using remestemcel-L in 241 children treated under an expanded access protocol, where Day 28 OR correlated with Day 100 survival.
>
> * * *

[1] Unless otherwise stated, all emphases hereinafter are added.

> ***Based on interactions with the FDA, Mesoblast believes that successful results from the completed Phase 3 trial, together with Day 180 safety and quality of life parameters in these patients, may provide sufficient clinical evidence for filing for accelerated approval of remestemcel-L in the United States.*** The Phase 3 trial is being conducted under a FDA Investigational New Drug Application (NCT#02336230).

(Footnotes omitted.)

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on April 16, 2019. On that day, Mesoblast announced that the FDA agreed that the Company can "submit on a rolling basis" a BLA for remestemcel-L in children with SR-aGHVD. According to the Company, this process would "provide opportunity for ongoing and frequent communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA."

22. On May 29, 2019, Mesoblast announced that it had filed the first component of its rolling submission of its BLA for remestemcel-L for SR-aGVHD. The Company repeated that this "rolling process will provide opportunity for ongoing communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA."

23. On August 29, 2019, Mesoblast announced its operational progress and financial highlights for the fiscal year ended June 30, 2019 in a press release. Therein, regarding the BLA and market opportunity for remestemcel-L, the Company stated, in relevant part:

> **Graft Versus Host Disease**
>
> There are more than 30,000 allogeneic bone marrow transplants performed annually worldwide, primarily in patients being treated for blood cancers. The most severe forms of the disease, Grades C/D or III/IV, are frequently refractory to steroid therapy and associated with mortality rates as high as 90%.
>
> There are no approved therapies for aGVHD in the United States for children under 12.

In Mesoblast's Phase 3 trial of 55 children with aGVHD - 89% of whom had Grade C/D disease - treatment with remestemcel-L resulted in a six-month survival of 69%. In addition, achievement of an Overall Response at Day 28, which occurred in 69% of patients, predicted highest survival at Day 100 and Day 180, which was 85% and 79%, respectively. The trial successfully met its primary endpoint of increased Day 28 Overall Response compared with a protocol-defined historical control rate of 45% (p=0.0003). These data are consistent with prior results from an Expanded Access Program in 241 children where remestemcel-L was used as salvage therapy after failure of steroids and other agents.

Remestemcel-L is administered to patients in a series of intravenous infusions. Remestemcel-L has demonstrated immunomodulatory properties to counteract the inflammatory processes that are implicated in aGVHD by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

Potential United States Market for Remestemcel-L

The product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast's United States commercial strategy for remestemcel-L in aGVHD. The Company believes that the United States addressable market opportunity for remestemcel-L in aGVHD in children and adults is approximately eight times larger than Japan given differences in population size, incidence of aGVHD, and relative pharmacoeconomics.

Mesoblast is preparing for potential product launch in the United States of remestemcel-L for aGVHD in children. Health economics and outcomes research data presented by Mesoblast at the 24th European Hematology Association Congress indicated that pediatric aGVHD may result in significant deterioration in quality of life and additional direct healthcare costs of an average of up to US$500,000 per patient. This represents a significant commercial opportunity for Mesoblast's first potential product launch in the United States.

Filing for FDA approval

The rolling Biologics License Application (BLA) submission to the FDA is underway and we expect to complete the filing in CY2019. Remestemcel-L has received Fast Track designation for aGVHD and under this designation Mesoblast can request a priority review once its BLA filing is accepted by the FDA.

Commercial Activities for Potential Launch in United States

In line with our expected timelines for potential United States launch of remestemcel-L, Mesoblast has increased expenditure on commercial

> manufacturing activities and commercial team ramp up in parallel with its FDA filing activities.

(Footnotes omitted.)

24. On January 2, 2020, the Company announced that it had submitted clinical efficacy and safety data to the FDA in connection with its BLA for remestemcel-L. In a press release, Mesoblast stated, in relevant part:

> Mesoblast . . . announced that the United States Food and Drug Administration (US FDA) has confirmed receipt of Mesoblast's filing of clinical efficacy and safety data for remestemcel-L in its rolling Biologics License Application (BLA) for the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD). The final module will be filed during January, and Mesoblast will request an expedited FDA review of the BLA under the product candidate's existing Fast Track designation. If approved, remestemcel-L is planned to be launched in the US in 2020.
>
> ***The clinical submission included analyses of 309 children with SR-aGVHD who have received remestemcel-L across three separate studies.*** In addition, Mesoblast provided new data in control pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC) to provide an unbiased and independent estimate of response rates and outcomes in matched pediatric control patients treated with institutional standard of care.
>
> ***The results of the comparative analysis between Mesoblast's open-label Phase 3 study and contemporaneous controls receiving institutional standard of care demonstrate the effectiveness of remestemcel-L in this patient population***, with particular efficacy and survival benefit in patients with the most severe forms of aGVHD. These conclusions are supported by prior results from an Expanded Access Program in 241 children where remestemcel-L was used as salvage therapy after failure of steroids and other agents.

25. On February 3, 2020, Mesoblast announced that "it has submitted its completed" BLA with the FDA. The Company "filed the final module of the rolling BLA submission, covering quality control and manufacturing, with the FDA on January 31."

26. On February 24, 2020, Mesoblast issued a press release entitled "Consistent Outcomes Using Ryoncil™ as First-Line Treatment or Salvage Therapy in 309 Children With Steroid-Refractory Acute GVHD." Therein, the Company stated:

Mesoblast Limited (Nasdaq:MESO; ASX:MSB) today announced that aggregated results from 309 children treated with Ryoncil™ (remestemcel-L) were presented at the American Society for Transplantation Cellular Therapy and the Center for International Blood & Bone Marrow Transplant Research (TCT) meeting in Orlando, Florida on February 22. The data showed that treatment with RYONCIL across three separate trials resulted in consistent treatment responses and survival outcomes in children with steroid-refractory acute graft versus host disease (SR-aGVHD).

Key findings and conclusions were:

- Consistent safety and efficacy were observed across the continuum from first-line treatment after steroid failure through the most challenging patients who received RYONCIL as salvage after exhausting all other options.

- In the aggregated dataset, 204 of the 309 (66%) patients achieved an overall response at Day 28 following a four-week course of RYONCIL.

- Results were consistent across all grades of disease, including most severe (IBMTR Grade C/D or Glucksberg Grade 3/4).

- In the most severe patients (Grade C/D), who accounted for 82% of all treated patients, Day 28 overall response was 65%.

- Overall response at Day 28 was strongly predictive of survival at Day 100 and Day 180.

- Day 28 responders were more than twice as likely to survive as non-responders (84% vs 39% at Day 100, and 83% vs 38% at Day 180).

- RYONCIL was well tolerated with no infusion-related toxicity and no identified safety concerns.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "These aggregated data from three studies demonstrate consistent efficacy and safety of RYONCIL in children suffering from steroid refractory acute graft versus host disease. If approved, RYONCIL has the potential to be an effective and safe therapy to improve survival outcomes in the most vulnerable population of children with severe forms of this disease who can have mortality rates as high as 90 percent."

27. The above statements identified in ¶¶ 21-26 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) comparative

analyses between Mesoblast's Phase 3 trial and three historical studies did not support the effectiveness of remestemcel-L for steroid refractory aGVHD because of design differences between the four studies; (ii) as a result, the FDA was reasonably likely to require further clinical studies; (iii) as a result, the commercialization of remestemcel-L in the U.S. was likely to be delayed; and (iv) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

The Truth Begins to Emerge

28. On August 11, 2020, the FDA released briefing materials for its ODAC meeting to be held on August 13, 2020. Therein, the FDA stated that Mesoblast provided post hoc analyses of other studies "to further establish the appropriateness of 45% as the null Day-28 ORR" for its primary endpoint. The briefing materials stated that, because of design differences between these historical studies and Mesoblast's submitted study, "it is unclear that these study results are relevant to the proposed indication." Specifically, the briefing materials stated, in relevant part:

> The Applicant submitted the results of Protocol MSB-GVHD0011 to support their marketing application. Protocol MSB-GVHD001 was a prospective, multicenter, single-arm trial of remestemcel-L for treatment of pediatric patients with SR-aGVHD grades B-D (excluding grade B skin alone). The primary endpoint of the trial was the proportion of patients in the full analysis set (FAS) with overall response (defined as complete response (CR) + partial response (PR)) at 28 days after initiation of therapy. The protocol was designed to determine if the Day28 overall response rate (ORR) exceeded 45%. ***The study hypothesis and the null ORR were prespecified in the statistical analysis plan (SAP); however, the justification provided for the null rate in the Statistical Analysis Plan (SAP) was that it was 20 percentage points lower than that achieved with remestemcel-L in post hoc analyses of the pediatric subgroups in other protocols of remestemcel-L for treatment of aGVHD.***
>
> ***To further establish the appropriateness of 45% as the null Day-28 ORR, the Applicant also provided post hoc analyses of ORR*** in patients with SR-aGVHD treated with standard care therapies in the pediatric subgroup in the control arm of Protocol 280, pediatric patients with SRaGVHD in the Mount Sinai Acute GVHD International Consortium (MAGIC) database, and patients with newly-diagnosed

aGVHD who failed treatment with steroids but continued on steroids alone in Protocol 265.

* * *

Additional data were provided from Protocol 265, 275 and 280. In comparison to Protocol MSB-GVHD001, Protocols 265, 275 and 280 have substantial differences in the patient populations, trial design, study conduct, and primary endpoint evaluations:

- Difference in primary endpoints CR sustained > 28 days versus ORR at Day 28
- Differences in populations
  - ages (pediatric versus adult subjects)
  - disease state (newly diagnosed aGVHD versus SR-aGVHD)
  - disease stage (allowing grade B skin-only disease)
- Difference in treatment regimens
- The impact of concomitant medications (positively or negatively) on efficacy outcomes in Studies 280 and 275, particularly in light of the unknown mechanism of action of remestemcel-L.
- Limitations in reporting of DOR and variability in duration of follow-up (Day 180 versus Day 90)

Due to these design differences, it is unclear that these study results are relevant to the proposed indication for use of remestemcel-L as a single-agent treatment of SR-aGVHD in pediatric patients, but it raises the uncertainties associated with interpreting the observed efficacy outcomes between studies.

29. On this news, the Company's ADS price fell $6.09 per share, or approximately 35%, to close at $11.33 per share on August 11, 2020, on unusually heavy trading volume.

30. On August 14, 2020, the Company announced that the ODAC voted 9-to-1 in favor that "the available data support the efficacy of remestemcel-L (RYONCIL™) in pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD)." It stated that "[a]lthough the FDA will consider the recommendation of the [ODAC], the final decision regarding the

approval of the product is made solely by the FDA, and recommendations by the panel are non-binding."

31. On October 1, 2020, Mesoblast disclosed receipt of the CRL regarding its BLA for remestemcel-L for treatment of SR-aGVHD in pediatric patients. According to the CRL, the FDA recommended that the Company "conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD." The CRL also "identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity." Specifically, the press release stated, in relevant part:

> Mesoblast . . . announced today that the US Food and Drug Administration (FDA) has issued a Complete Response Letter to its Biologics License Application (BLA) for remestemcel-L for the treatment of pediatric steroid-refractory acute graft versus host disease (SR-aGVHD). While the Oncologic Drugs Advisory Committee (ODAC) of the FDA voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD, ***the FDA recommended that Mesoblast conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD.*** As there are currently no approved treatments for this life-threatening condition in children under 12, Mesoblast will urgently request a Type A meeting with the FDA, expected within 30 days, to discuss a potential accelerated approval with a post-approval condition for an additional study.
>
> * * *
>
> The FDA also identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity. Assays measuring the potency of remestemcel-L will continue to be refined to provide further scientific rationale for its use in severe inflammatory diseases with high mortality risk, such as SR-aGVHD and COVID-19 ARDS.

32. On this news, the Company's ADS price fell $6.56 per share, or over 35%, to close at $12.03 per share on October 2, 2020, on unusually heavy trading volume.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

33. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Mesoblast securities during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

34. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Mesoblast's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Mesoblast shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Mesoblast or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

35. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

36. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

37. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Mesoblast; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

38. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

39. The market for Mesoblast's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Mesoblast's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Mesoblast's securities relying upon the integrity of the market price of the Company's securities and market information relating to Mesoblast, and have been damaged thereby.

40. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Mesoblast's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Mesoblast's business, operations, and prospects as alleged herein.

41. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Mesoblast's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

42. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

43. During the Class Period, Plaintiff and the Class purchased Mesoblast's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information

alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

44. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Mesoblast, their control over, and/or receipt and/or modification of Mesoblast's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Mesoblast, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

45. The market for Mesoblast's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Mesoblast's securities traded at artificially inflated prices during the Class Period. On August 17, 2020, the Company's share price closed at a Class Period high of $19.81 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Mesoblast's securities and market information relating to Mesoblast, and have been damaged thereby.

46. During the Class Period, the artificial inflation of Mesoblast's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the

damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Mesoblast's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Mesoblast and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

47. At all relevant times, the market for Mesoblast's securities was an efficient market for the following reasons, among others:

(a) Mesoblast shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Mesoblast filed periodic public reports with the SEC and/or the NASDAQ;

(c) Mesoblast regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Mesoblast was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

48. As a result of the foregoing, the market for Mesoblast's securities promptly digested current information regarding Mesoblast from all publicly available sources and reflected such information in Mesoblast's share price. Under these circumstances, all purchasers of Mesoblast's securities during the Class Period suffered similar injury through their purchase of Mesoblast's securities at artificially inflated prices and a presumption of reliance applies.

49. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

50. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Mesoblast who knew that the statement was false when made.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

51. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

52. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Mesoblast's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

53. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Mesoblast's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as

primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

54. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Mesoblast's financial well-being and prospects, as specified herein.

55. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Mesoblast's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Mesoblast and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

56. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's

management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

57. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Mesoblast's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

58. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Mesoblast's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by

Defendants during the Class Period, Plaintiff and the other members of the Class acquired Mesoblast's securities during the Class Period at artificially high prices and were damaged thereby.

59. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Mesoblast was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Mesoblast securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

60. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

61. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

62. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

63. The Individual Defendants acted as controlling persons of Mesoblast within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had

the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

64. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

65. As set forth above, Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: October 30, 2020

Respectfully submitted,

POMERANTZ LLP

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Attorneys for Plaintiff

CERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS

1. I, ALAN MAUSKOPF, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against Mesoblast Limited ("Mesoblast" or the "Company") and authorize the filing of a comparable complaint on my behalf.

3. I did not purchase or acquire Mesoblast securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired Mesoblast securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

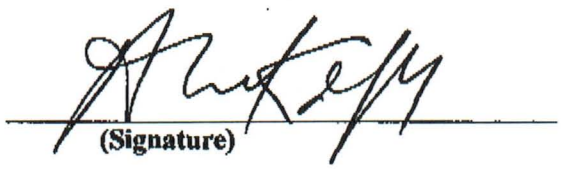
5. To the best of my current knowledge, the attached sheet lists all of my transactions in Mesoblast securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Executed October 12 2020
(Date)


(Signature)

Hans Mauskopf
(Type or Print Name)

Mesoblast Limited (MESO) **Mauskopf, Alan**

List of Purchases and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase	7/10/2020	200	$13.0200